

Application Serial No. 10/655,874
Amendment and Response dated March 14, 2005
Response to Office Action of September 13, 2004

REMARKS

Claims 1, 3, 5-6, 10, 11, 14, and 15 have been amended. No new matter is added by the Amendments. Claims 3, 9 and 18 have been cancelled. Claims 19-43 were withdrawn by the Examiner as being drawn to a non-elected invention. Therefore, claims 1-2, 4-8, 10-17, and 19-43 are pending in the application. Entry of the Amendment and reconsideration of the claims in view of the following Remarks is respectfully requested.

Specification

The Examiner objected to the specification, stating that not all trademarks are capitalized or accompanied by the generic terminology. Applicants have amended the specification to properly identify the trademarks. Withdrawal of the rejection is requested.

Drawings

Applicants acknowledge the Examiner's notation of the presence of color drawings. Applicants will provide new drawings or a petition under 37 C.F.R. 1.84(a)(2) at a later date.

Claim Objections

The Examiner objected to claim 1 for informalities. To speed prosecution of the case, claim 1 has been amended in accordance with the Examiner's suggestions. Withdrawal of the rejection is requested.

Claim 3 was also objected to for allegedly failing to further limit claim 2. Claim 1 has been cancelled. Withdrawal of the rejection is therefore requested.

Claim 18 was objected to as being a substantial duplicate of claim 8. Claim 18 has been deleted. Withdrawal of the rejection is requested.

Claims 4-17 were objected to as being dependent from a rejected base claim. As discussed below, all base claims are in condition for allowance. Withdrawal of the objection is therefore requested.

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35 USC § 102

Claims 1-3 were rejected under 35 U.S.C. 102(b) as being anticipated by WO 88/01624. Applicants respectfully traverse this rejection.

Amended claim 1 recites a process for extracting a heterologous target protein from *Escherichia coli* cells, comprising "lowering the pH of a solution containing whole *Escherichia coli* cells expressing a heterologous target protein to form an acidic cell solution," "adding at least one solubility enhancer to the solution containing the *Escherichia coli* cells," disrupting the cells to release the protein, and separating cellular debris from the released protein.

Applicants submit that WO 88/01624 nowhere teaches or suggests a process for extracting a heterologous protein from *Escherichia coli* cells comprising the steps recited in claims 1-3. Specifically, WO 88/01624 nowhere teaches or suggests lowering the pH and adding a solubility enhancer to an *E. coli* cell solution prior to, or contemporaneously with, disrupting the cells to release protein. Rather, this reference teaches a process for purifying recombinant human IL-1 by acid extraction that "simultaneously solubilizes the IL-1 and precipitates the bulk of the microbial proteins" (page 3 lines 5-7). Applicants submit, therefore, that claims 1-3 are patentable over WO 88/01624, at least for the foregoing reasons. Withdrawal of the rejection is requested.

Claim 1 was rejected under 35 U.S.C. 102(b) as being anticipated by Nye et al. Applicants respectfully traverse this rejection for the same reasons discussed above concerning WO 88/01624. Namely, this reference neither teaches nor suggests adding at least one solubility enhancer to a pH-lowered solution containing *Escherichia coli* cells, and disrupting the cells in this solution. Rather, Nye et al. discloses a method of purifying a recombinant isoform of human myelin basic protein (MBP) by mechanically disrupting the cells under acidic conditions (page 1136, second full paragraph). Nye et al. discloses that the simultaneous cell disruption and acid extraction solubilized the MBP such that "all of the recombinant MBPs were found in the soluble fraction." *Id.* Applicants respectfully submit, therefore, that claim 1 is patentable over Nye et al., at least for the foregoing reasons. Withdrawal of the rejection is requested.

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Summary

Applicants submit that the claims are in condition for allowance and notification to that effect is earnestly solicited. The Examiner is invited to contact Applicants' representative if prosecution may be assisted thereby

Respectfully submitted,

MERCHANT & GOULD

Date: 3/14/05

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